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Nine Lawsuits Over Recalled Similac Formula Selected for Initial Bellwether Trial Discovery + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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Nine Lawsuits Over Recalled Similac Formula Selected for Initial Bellwether Trial Discovery

AboutLawsuits.com reported:

With dozens of Similac recall lawsuits being pursued against Abbott Laboratories, each involving similar allegations that infants developed severe and sometimes fatal infections after being fed recalled infant formula products, a group of nine representative cases has been selected for a bellwether process, which is designed to gauge how juries may respond to certain evidence and testimony that will be repeated throughout the litigation.

The claims stem from a massive Alimentum, Elecare and Similac formula recall issued in February 2022, following the discovery that powdered products manufactured at a Michigan facility were contaminated with Salmonella Newport and Cronobacter sakazakii bacteria.

At least two infant deaths and hundreds of illnesses were reported by parents who fed the contaminated baby formula to their children, and subsequent investigations by the United States federal government safety standards and best practices at its facility for years, endangering infants for the sake of profits.

There are currently at least 80 product liability claims filed throughout the federal court system, but it is ultimately expected that hundreds of additional lawsuits will be filed over the next few years, paving the way for hold Abbott Laboratories responsible for injuries caused by a failure to keep its manufacturing facility properly sanitized.

Pfizer Sues Poland for Bailing on COVID Vaccine, Citing Shady EU Mega-Deal

Zerohedge reported:

In April 2021, the world learned that European Commission President Ursula von der Leyen had been negotiating the biggest contract ever sealed for 1.1 billion doses of COVID-19 vaccines via text messages back and forth with Pfizer CEO Albert Bourla.

And while those texts were "somehow" lost, Pfizer is now suing Poland — which, under the EU deal struck between von der Leyen and Bourla, is obligated to purchase its proportion to choke 60 million more doses than it did.

"Pfizer and BioNTech are seeking to hold Poland to its commitments for COVID-19 vaccine orders placed by the Polish Government, as part of their contract to supply the European Union signed in May 2021," a Pfizer spokesperson told Politico, adding that BioNTech is joining the lawsuit.

Fast forward to the aftermath of Poland's October election, which saw the opposition gain enough seats to potentially install Donald Tusk, a centrist figure, in power. Pfizer's lawsuit, potentially amounting to €1.2 billion, presents a formidable challenge for Tusk's administration. This is money Pfizer is not just about recouping losses but sending a stark message to other nations considering contract breaches.

Lilly's Zepbound Is Set to Be Another Hit Amid Weight-Loss Frenzy

Bloomberg reported:

Weight-loss drugs are everywhere these days. At the Oscars earlier this year, host Jimmy Kimmel worked Ozempic into his opening monologue. Ads for Wegovy have become a regular feature of the New York City subway system. And Zepbound, a new weight-loss drug making its U.S. debut any day now, is entering a market where it's all but guaranteed to become an overnight success.

But the typical TV ads and catchy jingles aren't what's behind the frenzy over appetite-suppressing drugs from Novo Nordisk A/S and Eli Lilly & Co. Big Pharma is, in fact, has hardly had to lift a finger.

Instead, a combination of pop culture, social media and third-party marketers looking to cash in on the hype have helped turn weight-loss drugs into household brand names that rival Viagra and Prozac. U.S. prescriptions for Ozempic, Wegovy and Mounjaro surged 300% in just two years through the end of September to become some of the best-selling of all time. The drugmakers are struggling to keep up with demand.

It's not that Lilly and Novo aren't promoting their drugs at all. From January to late November, Lilly and Novo have spent a combined $218 million on commercials for Ozempic and Mounjaro, diabetes drugs that have become popular for weight loss, according to Kantar. But together they account for just 3.7% of the whopping $5.8 billion pharmaceutical companies have spent on TV ads over this past year. Wegovy, Novo's weight-loss drug that's even yet had its national TV debut, according to iSpot.tv. The ads that have run for Ozempic and Mounjaro describe the drugs as medical interventions for people suffering from diabetes — not a miracle diet drug that can help anyone get fit with ease.

CDC: Last Year's Flu Shot Was Less Than 50% Effective for Children and Adolescents

The Epoch Times reported:

During the 2022-2023 flu season, the influenza vaccine was less than 50% effective at preventing emergency department/urgent care visits and hospitalizations among children and adolescents, according to a study funded by the Centers for Disease Control and Prevention (CDC).

The analysis, published Nov. 16, 2023, in Clinical Infectious Diseases, found the seasonal influenza vaccine was only 48% effective overall at reducing the risk of influenza-A-associated emergency department (ED) or urgent care (UC) visits, and only 40% effective at preventing hospitalizations.

"I dislike using the term 'cherry pick,' but without randomization and/or matching of cases with controls, we cannot rule out explicit and/or implicit biases made at the site, principal investigator, and provider levels in identifying subjects," Linda Wasilla, professor and Parke-Davis chair of geriatric pharmacology with a doctorate in health policy, told The Epoch Times. "In sum, based on the lack of matched cases/controls and lack of statistical control for covariates and confounders, at best, this study's findings reflect descriptive findings demonstrating associations, not causal or inferred effectiveness."

As reported by The Epoch Times, the CDC rolled out a digital ad campaign in September to rebrand the influenza vaccine and redefine expectations about what a yearly flu shot could and couldn't do amid breakthrough cases. The agency's new messaging is that the flu shot wouldn't prevent a person from getting sick but would prevent severe illness should one still get sick.

This is similar to the shift in messaging adopted by U.S. regulatory agencies with COVID-19 vaccines when breakthrough COVID-19 cases started piling up among the vaccinated. U.S. health officials then admitted the shots did not prevent COVID-19 or transmission of the virus to others, and vaccine efficacy was redefined by whether the vaccine prevented hospitalizations and death.

Virginia Localities Sue Pharmaceutical Giants Over Insulin Costs

The Washington Post reported:

Three local governments in Virginia are suing pharmaceutical giants Eli Lilly, Novo Nordisk and Sanofi-Aventis, alleging in federal court that the drugmakers have conspired for years with middleman companies known as pharmacy benefit managers to hike the price of insulin by hundreds of dollars.

In nearly identical lawsuits filed this month, an attorney representing the city of Alexandria and Arlington and Henrico counties argued that thousands of Virginians who need insulin to keep their diabetes in check have been harmed by "artificial" price hikes engineered by the three pharmaceutical giants and pharmacy benefit managers CVS Caremark, Express Scripts and OptumRx, which have significant market power that gives them influence in setting prices for prescription medications.

According to the lawsuits, the cost of producing a vial of insulin has decreased in the last two decades and is currently about $2, but the price for consumers has soared — from about $20 in the 1990s to a current range of $300 to $700.

Other states and countries across the country, including California, Kansas, Minnesota and Mississippi, have filed similar legal complaints over insulin prices. A federal judge in New Jersey is overseeing a case combining more than a dozen such lawsuits by states and local governments.

Novo Nordisk Keeps GLP-1 Expansion Spree Rolling With $2.3 Billion Manufacturing Upgrade in France

Fierce Pharma reported:

After plotting $6 billion in production upgrades earlier this month, Novo Nordisk's CEO Lars Fruergaard Jørgensen suggested the expansion outlay was just the start. Now, some three weeks later, he's putting his company's money where his mouth is.

Starting this year, Novo Nordisk will plug more than 16 billion Danish kroner ($2.3 billion) into an expansion of its long-held production site in Chartres, France. The upgrade will help the site crank out current and future drugs for serious chronic diseases, Novo said in a release.

The outlay is designed to boost Novo Nordisk's ability to meet future demands for its drugs, including GLP-1 products, the company explained.

Novo's semaglutide franchise of GLP-1s — which includes Ozempic and Rybelsus for diabetes, as well as Wegovy for obesity — has been driving gangbusters in recent years. But intense demand for the products has also saddled Novo with supply constraints.

Sanofi Looks to Widen Dupixent Use to Treat 'Smoker's Lung' After Second Trial Win

Reuters reported:

Sanofi (SASY.PA) plans to seek U.S. approval for its best-selling anti-inflammatory drug Dupixent to be used in the treatment of "smoker's lung," also known as COPD, after a second large trial showed significant benefits.

Sanofi and Regeneron, which have been testing the drug on current and former smokers who can't control their COPD with established inhalers, had embarked on the second trial to bolster the statistical reliability of the read-outs.

COPD, which damages the lungs progressively, is the third leading cause of death worldwide. It can also be caused by air pollution and related occupational hazards.

Sanofi shares rose as much as 2.6% and were up 0.9% by 0953 GMT. Lining Dupixent for COPD could add billions to the French drugmaker's growth prospects. It would, however, also increase its already heavy reliance on the drug which is currently used to treat eczema, asthma and other inflammatory conditions.

Japan Panel Recommends Approval of Updated Daiichi sankyo COVID Shot — Kyodo

Reuters reported:

A Japanese health ministry panel on Monday recommended approval for an updated version of Daiichi Sankyo's (4568.T) COVID-19 vaccine, the Kyodo news agency said.

The mRNA-based shot was initially approved as a booster in August, becoming Japan's first home-grown shot for the coronavirus. The vaccine was updated to provide protection against the XBB.1.5 Omicron subvariant, a contingent for the health ministry to buy 1.4 million doses.

Separately, the panel recommended approval for a self-amplifying mRNA vaccine for the coronavirus that was submitted by the pharmaceuticals unit of Meiji Holdings (2269.T), Kyodo said. Meiji in April acquired the Japanese rights to the shot, developed by San Diego-based Arcturus Therapeutics (ARCT.O).

Australia Needs New Adult Vaccination Plan for COVID, Flu and Shingles, Report Warns

The Guardian reported:

Governments should create a national plan to make adult vaccination as robust as childhood vaccines, as rates lag across dangerous diseases and misinformation increases, according to a new report.

A Grattan Institute report published on Monday has found Australia "urgently needs a policy reset," with data showing rates of adult vaccination against COVID, flu, shingles and pneumococcal disease are far too low.

The report also highlights that rates of COVID-19 vaccination have "plunged," with 2.5 million people over the age of 65 not up-to-date with their vaccinations at the start of winter 2023 — 2 million more than a year earlier.

Britain Detects First Human Case of Flu Strain Similar to Pig Virus

Reuters reported:

Britain said on Monday it had detected a first human case of flu strain A(H1N2)v, which is similar to a virus currently circulating in pigs, and that the individual concerned had experienced a mild illness and fully recovered.

The U.K. Health Security Agency (UKHSA) said that the case was detected as part of routine national flu surveillance and the source of infection was not known.

"This is the first time we have detected this virus in humans in the U.K., though it is very similar to viruses that have been detected in pigs," UKHSA incident director Meera Chand said.

The UKHSA said that based on early information the infection detected recently in Britain was different from the 50 or so other human cases of the strain found elsewhere globally since 2005.

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